

Docket N .: PF-0622 USN

APPENDIX

31. An isolated polynucleotide selected from the group consisting of:

- a) a polynucleotide comprising the polynucleotide sequence of SEQ ID NO:9,
- b) a polynucleotide complementary to the polynucleotide of a),
- c) an RNA equivalent of a) or b).

32. A method of detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 31, the method comprising:

- a) hybridizing the sample with a probe comprising at least 20 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide, and
- b) detecting the presence or absence of said hybridization complex, and, optionally, if present, the amount thereof.

33. A method of claim 32, wherein the probe comprises at least 60 contiguous nucleotides.

34. A method of detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 31, the method comprising:

- a) amplifying said target polynucleotide using polymerase chain reaction amplification, and
- b) detecting the presence or absence of said amplified target polynucleotide and optionally, if present, the amount thereof.

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Exhibit A

8090 743-1313 P. 13rd INC.
FEB 11 2004
SEARCHED

APR 28 2003



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,088	05/01/2001	Y. Tom Tang	PF-0622 USN	8378

7590 04/21/2003

Incyte Genomics Inc
Legal Department
3160 Porter Drive
Palo Alto, CA 94304

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/21/2003 (5)

Please find below and/or attached an Office communication concerning this application or proceeding.

Incyte Genomics Inc.
Plaintiff Corp. Legal Dept.
Received

APR 25 2003

Office Action Summary

	Application No.	Applicant(s)
	09/831,088	TANG ET AL.
	Examiner	Art Unit
	Richard G Hutson	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Partial Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 February 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-36 is/are pending in the application.
 4a) Of the above claim(s) 21-23, 27-30 and 32-36 is/are withdrawn from consideration.
 5) Claim(s) 24-26, 31 is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.

- 4) Interview Summary (PTO-413) Paper No(s) 15.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other:

Interview Summary	Application No.	Applicant()
	09/831,088	TANG ET AL.
	Examiner Richard G Hutson	Art Unit 1652

All participants (applicant, applicant's representative, PTO personnel):

(1) Richard G Hutson.

(3) _____.

(2) Shirley Recipon.

(4) _____.

Date of Interview: 17 April 2003.

Type: a) Telephonic b) Video Conference
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.
If Yes, brief description: _____.

Claim(s) discussed: 24-26 and 31-34.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
 A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR 51.2 Business to be transacted in writing.
 All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case, unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted.
- 2) An identification of the claims discussed.
- 3) An identification of the specific prior art discussed.
- 4) An identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner.
- 5) A brief identification of the general thrust of the principal arguments presented to the examiner.
 (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) A general indication of any other pertinent matters discussed, and
- 7) If appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation Sheet (PTO-413)

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The examiner called applicant's representative to discuss the correction of formal matters to put the instant application in condition for allowance, specifically the cancellation of claims drawn to non-elected subject matter. Applicants indicated that they thought that newly added claims 32-34 were drawn to methods of detecting a target polynucleotide having the sequence of a polynucleotide of claim 31 were subject to rejoinder. The examiner informed applicant's representative that claims 32-34 were not subject to rejoinder as they were not drawn to either a method of use or a method of making the polynucleotide of Group II. The examiner indicated to applicant's representative that the referred to claims, 32-36, were drawn to methods of use of a genus of polynucleotides that were considerably broader than the elected group. The applicant's representative disagreed with the examiner's interpretation and asked that an action be sent out so that applicant's representative would have more time to consider the issue.

Application/Control Number: 09/831,088
Art Unit: 1652

Page 2

DETAILED ACTION

Applicants preliminary amendment canceling claims 1-20 and adding new claims 21-36, Paper No. 13, 1/30/2003, is acknowledged. Claims 21-36 are at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group II, Claims 23-26, 28, 30 and 31 in Paper No. 13 is acknowledged. Applicant's further election with traverse of SEQ ID NO: 91, Claims 24-26, 28 and 31 in Paper No. 13 is acknowledged. Applicants traverse the restriction requirement on several grounds.

First, applicants traverse the restriction requirement between Groups II and VII (III?) on the basis that the claimed methods are dependent on knowing the sequence of the polynucleotide of claim 31 and therefore a search of these two groups would substantially overlap and would thus not be an undue burden on the examiner. This argument is not found persuasive because knowing the sequence of the polynucleotide of claim 31 is not necessary to practice the invention of Group III (a method of detecting a polynucleotide) and the searches of these groups while overlapping are not coextensive and thus would cause an undue burden on the examiner.

Second, applicants traverse the restriction requirement between elected Group II drawn to polynucleotides and Group I drawn to polypeptides on the basis that many of the claimed polynucleotides encode the claimed polypeptides and thus a search for th

Page 3

Application/Control Number: 09/831,088

Art Unit: 1652

polynucleotides would include the polypeptides which they encode. Applicants argument is not found persuasive because while the searches for the each of the groups overlap, they are not coextensive. For example, search of Group I would require search of subclass 530/350, a search of which would be unnecessary for the search of the elected group II. The reference applicants present in support of their reasons to maintain the different Groups together is not found persuasive because the searches necessary for a complete determination of novelty and un-obviousness requires more than a search of such a reference.

Third, applicants traverse the restriction requirement between Groups I and IV and hence Group II on the basis that these Groups could be examined at the same time also without undue burden on the examiner, as a search of the prior art for each of the groups would substantially overlap. As above this argument is not found persuasive because while the searches for the each of the groups overlap, they are not coextensive. For example, search of Group IV would require search of subclass 530/387.1, a search of which would be unnecessary for the search of the elected group

II.

Applicants traverse the restriction requirement between elected Group II drawn to polynucleotides and newly added claim 27 drawn to a transgenic organism, as above, on the basis that a search of the different Groups would substantially overlap. It is noted that the invention of this newly added claim was not included in the original claim set, however as discussed above with respect to groups I and III, while the search of elected Group II and claim 28 would overlap, they are not coextensive. For example,

Page 4

Application/Control Number: 09/831,088

Art Unit: 1652

A search of the subject matter of claim 28 would require search of subclass 800/13, a search of which would be unnecessary for the search of the elected group II.

Applicants further traverse the restriction requirement between elected polynucleotide of SEQ ID NO: 9 and those of SEQ ID NOs: 1-3, 5, and 6-8 on the basis that these claims are written as part of a Markush group. This argument is not found persuasive on the basis that the newly added claims are not drawn to a group that are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without a serious burden (i.e. 7 independent and distinct polynucleotide and polypeptide sequences). Further applicants have not disclosed what common utility each of the members of the group share nor have applicants disclosed the substantial structural feature disclosed as being essential to that utility.

Applicants comments with respect to the rejoinder of claims 32-34 are also acknowledged, however as discussed above, the methods of claims 32-34 are not subject to rejoinder as they do not recite methods of using the allowable product but instead methods of using fragments of the allowable product.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-23, 27-30, 32-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 13.

Information Disclosure Statement

Application/Control Number: 09/831,088

Page 5

Art Unit: 1652

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosures, Paper No. 14, filed 2/6/2003, is acknowledged. Those references considered have been initialed.

Allowable Subject Matter

Claims 24-26 and 31 are allowable over the prior art.

This application is in condition for allowance except for the following formal matters:

This application is in condition for allowance except for the presence of claims 21-23, 27-30, 32-36 to an invention non-elected with traverse in Paper No. 13.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Application/Control Number: 09/831,088
Art Unit: 1652

Page 6

The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest a polynucleotide encoding the acyl-CoA synthetase enzyme of SEQ ID NO: 4.

Interview Summary Enclosed

As noted in the enclosed interview summary, the examiner called applicant's representative to discuss the correction of formal matters to put the instant application in condition for allowance, specifically the cancellation of claims drawn to non-elected subject matter. Applicants indicated that they thought that newly added claims 32-34 drawn to methods of detecting a target polynucleotide having the sequence of a polynucleotide of claim 31 were subject to rejoinder. The examiner informed applicant's representative that claims 32-34 were not subject to rejoinder as they were not drawn to either a method of use or a method of making the polynucleotide of Group II. The examiner indicated to applicant's representative that the referred to claims, 32-36, were drawn to methods of use of a genus of polynucleotides that were considerably broader than the elected group. The applicant's representative disagreed with the examiner's interpretation and asked that an action be sent out so that applicant's representative would have more time to consider the issue.

Page 7

Application/Control Number: 09/831,088

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.
Primary Patent Examiner
Art Unit 1652
April 21, 2003



U.S. Department of Commerce, Patent and Trademark Office	Atty Docket No.	Serial No.
	PP-0622 USN	09/831,088
LIST OF REFERENCES CITED BY APPLICANTS <i>(Use several sheets if necessary)</i>		Applicant(s)
		Tang et al.
		Filing Date
		May 1, 2001
		Group 1652

Examiner

Date Considered

4/13/03

[Signature]
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.